CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

FACTS

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Rapid HIV Tests: Questions/Answers

General Questions

What has been the routine test for HIV antibody testing?

The standard screening test for antibody to HIV is the enzyme immunoasssay (EIA), which is widely used in the United States and around the world. This test requires serum or plasma, so a blood specimen must be drawn from a vein. Because EIA requires specialized equipment, the specimen must be sent to a laboratory, and test results are usually available several days to several weeks later. A negative screening test means a person is not infected with HIV, and does not require further testing. However, a diagnosis of HIV infection cannot be based on a reactive screening test alone. Thus, a reactive EIA is repeated, and repeatedly reactive EIA results are confirmed by a supplemental HIV antibody test --Western blot or immunofluorescence assay (IFA).

Until now, testing required two visits. During the first visit, a client receives pretest counseling, and blood is drawn for HIV testing. During the second visit, test results are communicated to the client, additional counseling is provided, and clients who need them are given referrals for additional services.

What is rapid HIV testing?

A rapid test for detecting antibody to HIV is a screening test that produces very quick results, usually in 5 to 30 minutes. The only rapid HIV test licensed by the Food and Drug Administration (FDA) for use in the United States is the Single Use Diagnostic System for HIV-1 (SUDS), manufactured by Murex.* (See the list of resources at the end of these questions and answers.)

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* Use of trade names and commercial sources is for identification only and does not imply endorsement by the Public Health Service or the U.S. Department of Health and Human Services.

What is the difference between a rapid HIV test and an EIA?

The rapid HIV test is easier to use and produces results more quickly than the EIA does. The sensitivity and specificity of the rapid HIV test are just as good as those of the EIA.

What rapid HIV tests are available?

Currently, the only FDA-licensed rapid HIV test is SUDS*. (See the list of resources at the end of these questions and answers.)

Will other rapid HIV tests be available in the future?

Several other rapid HIV tests are being used in many other countries. Still others, including one for use with oral fluids, are being developed. The new generation of rapid HIV tests may be quicker and easier to use than SUDS.

Who can be tested with a rapid HIV test?

Rapid HIV testing is suitable for testing any person who would be eligible for HIV testing by EIA. However, the availability of rapid HIV tests may differ from one place to another. (See the list of resources at the end of these questions and answers.)

Does the rapid HIV test cost more than the EIA?

Yes. The individual kit is more costly then the per-test cost of the EIA. EIA testing was designed for the automated processing of tests in batches (usually using a plate that can process 96 specimens at one time.) However, an analysis done in 1996 by Dr. Paul Farnham and his colleagues at CDC indicated that rapid HIV testing is more cost-effective than the current EIA-based system, because of the number of persons who actually learn their results. In other words, although EIA is less expensive, it is a waste of money to perform lab tests if the person tested never learns the test result, if two clinic visits are required to get test results, or if the clinic has to send field staff to locate people for test results. Since an EIA does not yield immediate results, most people must make a second visit to learn their results. Experience at publicly funded testing sites has shown that many persons (26% of those who tested positive for HIV and 33% of those who tested negative in 1996) do not return for their test results.

Can I expect to see rapid HIV testing in most clinics and doctors' offices soon?

Probably. It is difficult to know how soon this will take place.

Are rapid HIV tests more accurate or less accurate than EIAs?

The rapid HIV test is just as accurate as an EIA. As is true of all screening tests (including the EIA), a reactive rapid HIV test result must be confirmed. Studies in countries where more than one type of rapid HIV test is available show that specific combinations of two or more different rapid HIV tests can provide results as reliable as those from an EIA and Western blot or IFA, the combination that is currently used in the United States. A second rapid HIV test for persons whose first rapid HIV test is reactive could significantly improve the predictive value of rapid HIV testing.

What is predictive value?

Predictive value is the calculated probability that a test result predicts whether a person is truly infected. This calculation produces a number that counselors can use in explaining HIV test results to their clients. For example, a higher predictive value means that a reactive test is more likely to indicate the person is truly infected.

If a person receives a negative rapid HIV test result, is a confirmatory test needed?

A negative antibody test result, whether it is from a rapid HIV test or an EIA, does not require a confirmatory test. However, a person may have been tested too soon, before antibodies developed. The average time between infection and the development of detectable antibodies is 25 days.

Does a negative rapid HIV test result mean that a person has nothing to worry about?

Not necessarily. For most people who are tested, a negative HIV antibody test result does mean that they are not infected. However, in some cases a person may have been tested too soon (before antibodies have developed, which requires an average of 25 days). That is why it is important to assess specific risk behaviors during counseling, and discuss ways to change risky behaviors.

What is a "reactive" HIV test result?

The term "reactive" is used to describe a test that has detected the presence of antibodies to HIV. It is recommended that all reactive tests be repeated immediately, by using the same test. Repeatedly reactive tests are then further confirmed, by using a different test on the same blood specimen.

After a reactive rapid HIV test result, how long does a person have to wait for the confirmatory test result?

The confirmatory tests are usually sent to a laboratory for processing; results are generally available in 1 to 2 weeks.

Questions – Technical, Counseling, and Implementation

What is the cost of a rapid HIV test?

Prices may be different in different parts of the country. The SUDS test kit usually costs $6 to $10, which is more expensive than an EIA. However, the EIA requires expensive equipment and rapid HIV tests do not. Additional costs such as a laboratory or a laboratory technician's time for conducting the tests should also be considered. Rapid HIV tests are simpler to perform and require fewer specialized skills than does an EIA.

Can CDC HIV prevention funds be used to pay for rapid HIV tests?

Yes. CDC prevention funds can be used to support any FDA-approved HIV testing service.

If a confirmatory test is still needed, what is the advantage to sexually transmitted disease (STD) clinics of using rapid HIV testing?

The advantage to the clinic is that more people will receive their test results without expensive field visits. Most of the clients at all U.S. publicly funded testing sites, including STD clinics, test negative for HIV. For these persons (approximately 2.1 million in 1996), the need to make a second visit would be eliminated. Of all testing sites, STD clinics have had the lowest proportion of persons who return for HIV test results. Thus, rapid HIV tests have the potential to greatly increase the number of persons who learn their results. In addition, persons who test HIV-positive by the rapid HIV test can be advised immediately of their screening test result, and counseled about the need to take precautions to prevent the possibility of transmitting HIV. These persons of course need to return for their confirmatory test result.

What is the advantage to clients of using rapid HIV testing?

Interviews with persons being tested indicate that most persons prefer rapid HIV testing, and most persons who receive a positive HIV screening test result return on their own to learn the confirmed result (unlike the situation with current testing, in which many persons learn their test results only as a result of outreach). This also means that persons who are truly HIV-positive will learn of their infection sooner. This may help prevent infections that might otherwise have occurred between the time the person was tested and the time the person received results (sometimes as long as several weeks.)

Will people who have progressed to the late stages of AIDS continue to test positive on the rapid HIV tests?

Yes. The progression of HIV disease rarely affects the detection of HIV antibody.

Can rapid HIV tests be performed on infants?

The result of any HIV antibody test performed on an infant less than 15 months of age may reflect the mother's HIV status, because the antibodies are transferred from the mother to the baby. Until these antibodies disappear, only specific virus detection tests can determine the infection status of an infant.

Can clinic staff batch rapid HIV tests?

Yes. Batching, or collecting several specimens before testing all of them at the same time, can be done. This process can save money for a busy clinic, because fewer control test kits are required. However, accumulating a sufficient number of tests for a batch can result in excessive waiting time for the client, reducing the main benefit of the rapid HIV test: rapid results.

How long does the rapid HIV test take after the lab receives the specimen?

The SUDS rapid HIV test usually takes 15 to 30 minutes. The waiting time depends on how many clients are being tested and whether the clinic is testing individual samples or batching them. Counseling can be performed while the test is being done.

What type of training will be available for HIV counselors at sites that use rapid HIV tests?

CDC is developing new guidance and training for counselors. (See the list of resources at the end of these questions and answers.)

Are educational materials (e.g., handouts, videos) available for the clinics that want to use rapid HIV tests?

CDC will assist counselors and others who plan to develop such products. The manufacturers of rapid HIV tests usually have such materials as well.

Would telephoning clients to provide the results of a positive confirmatory HIV test be acceptable?

Current CDC counseling and testing guidelines state that positive HIV results should be communicated by personal contact. Whether this personal contact is established by phone or in person is a decision to be made at the local level.

What does the counselor tell a client who has a reactive rapid HIV test?

One of the more challenging counseling issues is how to communicate reactive rapid HIV test results to clients without the benefit of a same-day confirmatory test result. Counselors should be able to discuss with the client the likelihood of whether the rapid HIV test result means the client has HIV infection. This discussion should be based on the prevalence of HIV among persons tested at that clinic coupled with an assessment of the client's risk behaviors. In clinics that usually experience a high prevalence of HIV infection among their clients, a reactive rapid HIV test result is more likely to represent a true infection, especially in persons who report risk behaviors for HIV. Any person whose rapid HIV test is reactive should be counseled about the need to take precautions to prevent any possibility of transmitting HIV infection until their infection status has been determined by a confirmatory HIV test.

Do you start partner notification and referral services immediately upon receiving a reactive rapid HIV test result, or do you wait for the confirmatory test result?

Partner notification and referral services should not be initiated until the reactive rapid HIV test result has been confirmed.

Should a physician prescribe antiretroviral treatment for a pregnant woman on the basis of rapid HIV test results (per the PHS Guidelines)?

A negative rapid HIV test of course means that antiretroviral treatment is not necessary. Deciding what to do about therapy when the rapid HIV test is reactive is more complicated. If the circumstances are not urgent, it would be preferable to wait for the confirmatory test result. In other circumstances (such as a rapid HIV test result for a woman in labor, for whom no other result is available), physicians should base decisions about antiretroviral treatment on the predictive value of the preliminary rapid HIV test results and an assessment of the mother's HIV risk. (CDC. Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Perinatal HIV-1 Transmission in the United States. *MMWR* 1998;47(No. RR-2):1-31.)

Are confirmatory tests necessary for a rapid HIV test result to be considered a diagnosis of HIV infection?

As is true of current EIA antibody procedure, an initial reactive rapid HIV test result should be confirmed by Western blot or IFA. For persons who test positive by confirmatory testing, CDC and the Association of State and Territorial Public Health Laboratory Directors recommend that the test sequence be repeated, by using a different sample, to be absolutely certain of the results.

Resources

For information on referrals to counseling and testing sites, contact

CDC National AIDS Hotline

(English) 800-342-2437

(Spanish) 800-344-7432

(TTY) 800-243-7889

CDC Educator/Trainer Network -- HIV Prevention Counseling Trainers and Counselors

Sheila Cort Isoke, MPH

CDC, National Center for HIV, STD, and TB Prevention

(telephone) 404-639-0962

(fax) 404-639-0944

(e-mail) shc1@cdc.gov

CDC-sponsored training for performing HIV testing

National Laboratory Training Network

(telephone) 770-488-7811

CDC Division of HIV/AIDS Prevention Internet Homepage

http://www.cdc.gov/nchstp/hiv_aids/dhap.htm

For information on SUDS

Murex Diagnostics, Inc.

3075 Northwoods Circle

Norcross, GA 30071

(telephone) 800-334-8570

(fax) 770-449-4018 (fax)

(Web site) www.int-murex.com